

Rec'd PCT/PTO 28 APR 2005

PCT/US03/34441-24112004  
PAGE 6/7 RCV'D AT 11/24/2004 11:00:49 AM Eastern Standard Time SVS-USPTO-EXR-20 DMS-746092 CSU-001M

Attorney Docket CSU-001M

1 PEA/US

We claim:

1. A method of modulating physiological and pathophysiological conditions mediated by androgens in a mammal, comprising the step of administering to the mammal an effective amount of an enantiomeric equol that can bind with free 5 $\alpha$ -dihydrotestosterone, thereby inhibiting the binding of 5 $\alpha$ -dihydrotestosterone with the androgen receptors in the mammal and mediating the conditions mediated by the androgen.
2. The method according to ~~Claim 1~~ Claim 1, wherein the physiological and pathophysiological conditions is selected from the group consisting of: benign prostatic hyperplasia, prostate cancer, male and female pattern baldness, facial and body hair, acne, excessive secretion of sebum from the sebaceous glands, skin effects, anti-aging, anti-photoaging, skin integrity, skin pigmentation, skin whitening, Alzheimer's disease, emotions and mental health, depression, anxiety, Tourette's disease, Kennedy's syndrome, congenital defects in steroidal hormone synthesis and metabolism involving androgens, obesity, body weight, lipid and cholesterol levels, lipogenesis, lipolysis, inhibiting insulin resistance, blood pressure, thyroid function, and cardiovascular disease.
3. The method according to Claim 1 wherein the equol is administered as an oral composition comprising at least 1 mg enantiomeric equol.
4. The method according to Claim 1 wherein the equol is administered as a topical composition comprising at least 0.1% enantiomeric equol.
5. The method according to Claim 1, wherein the equol is administered as a composition comprising essentially an R-equol enantiomer.
6. The method according to Claim 1 wherein the equol is administered as a composition comprising a non-racemic mixture of R-equol and S-equol enantiomers.

AMERICAN STREET

BEST AVAILABLE COPY

Rec'd PCT/PTO 28 APR 2005

PCT/US03/34441.24112004  
 PAGE 7/7 \* RCVD AT 11/24/2004 11:00:49 AM [Eastern Standard Time] \* SVR-USPTO-EFEXF-20 \* DUNS-7465092 \* CSID:613 622 0893 \* QUPATTION (mm:ss) 03:26  
 Attorney Docket CSU-001M

1 PEA/US

7. A method of treating and preventing an androgen-related disease in a mammal, comprising the step of administering to the mammal an effective amount of an enantiomeric equol that can bind with free 5 $\alpha$ -dihydrotestosterone, thereby inhibiting the binding of the 5 $\alpha$ -dihydrotestosterone with the androgen receptors in the mammal.
8. The method according to Claim 7, wherein the androgen-related disease is selected from the group consisting of: benign prostatic hyperplasia, prostate cancer, male and female pattern baldness, facial and body hair, acne, excessive secretion of sebum from the sebaceous glands, skin effects, anti-aging, anti-photoaging, skin integrity, skin pigmentation, Alzheimer's disease, abnormal emotions and mental health, depression, anxiety, Tourette's disease, Kennedy's syndrome, congenital defects in steroidal hormone synthesis and metabolism involving androgens, obesity, abnormal body weight, abnormal lipid and cholesterol levels, excessive lipogenesis, lipolysis, inhibiting insulin resistance, high blood pressure, thyroid function, and cardiovascular disease.
9. The method according to Claim 7, wherein the equol is administered as a composition comprising essentially an R-equol enantiomer.
10. The method according to Claim 7 wherein the equol is administered as a composition comprising a non-racemic mixture of R-equol and S-equol enantiomers.
11. The method according to Claim 7 wherein the equol is administered as an oral composition comprising at least 1 mg enantiomeric equol.
12. The method according to Claim 7 wherein the equol is administered as a topical composition comprising at least 0.1% enantiomeric equol.
13. The method according to Claim 12 wherein said composition does not comprise a significant amount of any other androgen-receptor binding compound.
14. A method of modulating androgen hormone activity in a mammal, comprising the step of administering to the mammal an effective amount of an enantiomeric equol

AMENDED SHEET

that can bind with free 5 $\alpha$ -dihydrotestosterone, thereby modulating the binding of 5 $\alpha$ -dihydrotestosterone with the androgen receptors in the mammal.

15. A method of preventing DHT binding to the AR by contacting the DHT with an enantiomeric equol prior to the binding of DHT and AR.

16. A method according to Claim 15 wherein the contacting occurs *in vivo* in a mammal.

17. A method of treating and preventing a combination of an androgen-related condition and an estrogen-related condition in a mammal, comprising the step of administering to a mammal an effective amount of a mixture of R-equol and S-equol, that can bind with free 5 $\alpha$ -dihydrotestosterone, and with free 5 $\alpha$ -dihydrotestosterone and the estrogen receptor, respectively, thereby inhibiting the binding of the 5 $\alpha$ -dihydrotestosterone with the androgen receptors, and affecting binding of the estrogen receptors.

18. A method of modulating age-related androgen/estrogen hormonal balances, comprising the steps of:

- a. determining a mammal's endocrine androgen/estrogen hormone balance,
- b. administering to the mammal an effective amount of a mixture of R-equol and S-equol, that can modulate the hormone balance of 5 $\alpha$ -dihydrotestosterone and estrogen.

19. The use of an enantiomeric equol to bind *in vivo* free DHT, for modulating physiological and pathophysiological conditions mediated by androgens in a mammal.

20. A method of regulating the level of LH *in vivo* in a mammal by contacting the DHT of the mammal with enantiomeric equol.

21. The use of enantiomeric equol as a diagnostic agent for physiological and pathophysiological conditions mediated by androgens/androgen-related disorders effected by an estrogenic/androgenic imbalance.

22. The use of equol in a competitive binding assay, the assay comprising the steps of:

- 1) providing an androgen receptor,
- 2) providing a complex of DHT-enantiomeric equol,
- 3) providing a test substance comprising an androgen binding moiety, and
- 4) contacting and competing for the DHT-enantiomeric equol complex.